Outpatient Management of Chronic Diseases Using the TeleWatch Patient Monitoring System

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The number of Americans with chronic illnesses is rapidly increasing, and traditional health care delivery systems cannot adequately treat them. However, automated telemedicine systems may allow effective management of these patients. The TeleWatch Patient Monitoring System was designed at APL in collaboration with Johns Hopkins Medicine Division of Cardiology to study the effectiveness of a telephone-based telemedicine system in managing outpatients with chronic illnesses. The system is currently undergoing clinical studies in outpatients with chronic cardiovascular illness who are being treated by organizations affiliated with Johns Hopkins Medicine. Preliminary results indicate that patients are highly receptive to using the system.

INTRODUCTION

Because of declining fertility rates, decreasing childhood mortality, and increasing average lifespan in the "developed countries," the world's median age is increasing.[1] This demographic is more apparent in the United States, where people born in the two decades following World War II (i.e., the "baby boom") are beginning to reach retirement age while the relative percentage of young adults is declining.[2] The result of these worldwide and national demographic shifts is a dramatic increase in the absolute number and proportion of Americans over the age of 65. It is estimated that by 2030, 71 million Americans (19.6% of the population) will be older than 65, which is double the 35 million Americans who were older than 65 (12.4% of the population) in 2000.[2]

Concurrent with the aging of the population, the epidemiology of diseases affecting Americans is changing. At the dawn of the 20th century, acute illnesses such as infections, surgical emergencies, and injuries were the most prevalent form of illness in the United States, with the three leading causes of death in 1900 being pneumonia/influenza, tuberculosis, and infectious diarrhea/enteritis.[3] Over the past century, improved sanitation, access to water and food free of contamination, increased workplace safety, public health initiatives, and improved medical services have significantly reduced the morbidity and mortality of these acute and infectious illnesses. However, with Americans living longer, the effects of aging, genetics, diet, and lifestyle have resulted in high rates of chronic diseases such as heart failure, cancer, coronary artery disease, arthritis, diabetes, hypertension, and obstructive lung disease. At least 80% of Americans older than 65 suffer from at least one chronic illness, and more than 50% have at least two illnesses.[4] Whereas infectious diseases were the common causes of

death in 1900, by 1990 the three most common causes were heart disease, cancer, and stroke.[3]

Management of acute illnesses requires discrete and episodic care directed by medical personnel, often in a hospital or specialized medical environment. Patients and families are frequently passive bystanders in the process, and clinical outcome is generally binary: either cure or permanent disability/death. Once treatment is completed, there is little need for long-term patient monitoring or education. With near-universal access to emergency medical services, tiered acute-care hospitals, an abundance of procedure-based physicians, and advanced medications and medical devices, the American health care system is well suited to treat acute illnesses. However, the traits that make the system so effective at treating acute illnesses often make it ineffective at treating chronic illnesses.

By definition, chronic illnesses last at least 12 months; however, in practice they are usually lifelong conditions. The disease may transiently worsen and temporarily deteriorate and behave like an acute illness, but even with effective treatments of these acute exacerbations, the patient will continue to suffer from the underlying chronic process. Although medical personnel may direct the patient's overall medical treatment, the day-to-day care is delivered by the patient and family members, often within the patient's home. While proper medical treatment dictated by health care providers is an important component of treatment, patient-controlled components such as medication compliance, prompt identification of clinical deterioration, and self-initiated temporizing treatment in addition to diet, exercise, and health-related behaviors are equally, if not more, important. Unfortunately few patients or families have the level of medical knowledge or training required to adequately meet these needs. Therefore, proper management of chronic illnesses requires education of patients and families, frequent objective monitoring of the patient's clinical condition, and a pattern of regular contact and feedback from health care providers.

Educating patients about their chronic illnesses and the changes they must undertake to prevent future deterioration of their health is an important component of effective disease management. Although this type of education may be provided during office visits to the physician or hospitalizations, in practice studies show that these episodic education interactions are not very effective.[5] However, regularly scheduled, frequent, and interactive feedback with health care providers is a very effective way to teach patients to become more active in managing their illnesses. Research has shown that this form of follow-up improves clinical outcomes in patients with chronic illnesses.[6]

Effective outpatient management of chronic illnesses requires more than improved patient education because physiological changes, which may precede a clinical

deterioration, may go unnoticed by the patient. For instance, patients with asthma may have an impaired sensation of shortness of breath,[7] and patients with heart failure may subconsciously adapt their activity level to compensate for decreasing exercise tolerance. Both of these physiologic responses effectively "mask" the worsening symptoms from the patient, who is unaware of his or her own deteriorating health. Therefore, in addition to adequate education and feedback, patients with chronic illnesses also require some form of ongoing, objective, physiological evaluation to detect early changes consistent with a clinical deterioration, even in the absence of subjective complaints.

Frequent visits with health care providers, either in the home or in an office, can provide the necessary education, monitoring, and feedback for patients with chronic diseases; studies have shown that such approaches improve health and reduce medical expenses.[8] However, the frequency with which most health care providers can see outpatients who suffer from a chronic disease is limited. An increasing population of elderly patients, combined with a limited supply of health care providers and poorly reimbursed preventive health care claims, has resulted in increasing waiting times for patients to be seen by physicians. This is highlighted in a recent study showing that the percentage of patients waiting longer than 7 days to see a physician for an acute medical condition has increased from 22% in 1997 to 28% in 2001.[9]

Despite the necessity of frequent monitoring of outpatients with chronic illnesses, many components of this monitoring do not require face-to-face interaction with a physician. Most of the education, feedback, and monitoring of such patients entails relatively finite educational goals and relatively few physiological measurements, none of which require the presence of highly skilled health care providers. These measurements could conceivably be made by a computer-controlled system, enabling monitoring of multiple patients in parallel and allowing health care providers to concentrate time and resources on the few patients who lack knowledge or do not recognize evidence of clinical deterioration. Such a triage-based approach also leverages relatively few health care providers to care for significantly larger populations than would be possible in traditional outpatient practices.

Widespread acceptance of a computer-controlled system to monitor outpatients is predicated upon the technologies being readily familiar and easy to use by both patients and health care providers. Financial and logistical considerations also require that the monitoring systems be inexpensive, use readily available technology, and not require an extensive number of devices within the patient's home.

Based upon these constraints and considerations, the TeleWatch Patient Monitoring System was developed as

a joint venture between the Division of Cardiology of Johns Hopkins Medicine and APL. It was designed to be easy to use and simple to implement, and to incorporate technology familiar to patients. The system was exempted from regulatory oversight by the Food and Drug Administration in 2001. As a result, it can be used in clinical care.

THE TeleWatch SYSTEM

Overview

The TeleWatch System is a telephone-based, voice-interactive, automated telemedicine system that monitors patient-reported physiological measurements and symptoms. Patients make their own disease-appropriate physiologic measurements, which might include blood pressure, pulse, weight, serum glucose, and pulmonary spirometry using readily available, durable medical equipment. After making these measurements, patients access the TeleWatch System by placing a telephone call with a touch-tone phone to a computer that has a phone-interface connection board. Because no additional equipment is needed, patients can access the system from home, from work, or when traveling. As a result, patient mobility is markedly enhanced without degradation of the level of monitoring. In addition, since more than 95% of the population has access to and can use a telephone, a telephone-based approach ensures widespread accessibility to the system.

After calling the TeleWatch System, the patient's identity is authenticated when he or she enters a unique user ID and password. Once identity is authenticated, the patient hears a series of prerecorded voice files that ask a variety of questions specific to her/his medical condition. These questions have either binary yes/no, multiple choice, or numeric answers, and patients answer the questions with the telephone keypad. The TeleWatch System evaluates these answers in a real-time process. First a data validation algorithm detects improperly entered data and asks the patient to reenter any potentially improperly entered data to confirm the response. Then a rule-based algorithm asks additional questions if potential clinical abnormalities are detected. Depending on the length of the question set, this telephone interaction takes 2–5 min. If the system detects any abnormalities, an alert is automatically generated that notifies health care providers of the clinical problem and facilitates prompt intervention to treat the problem. By having the system monitor patient data and identify

responses that may indicate abnormalities, the system leverages the services of a small number of health care providers to treat a large number of patients and to respond to clinical deteriorations much more rapidly than is possible in the traditional health care delivery system.

Clinicians may view the clinical information that patients enter into TeleWatch from a central location or from satellite facilities that are connected to the central computer server via Virtual Private Networks or the Internet using secure socket layer protocol (Fig. 1). Data may be viewed for individual patients at a question-by-question level, or the patient's results can be graphically represented to aid in pattern recognition. In addition, physiological data and symptoms from the entire population that is being monitored by TeleWatch can be easily and rapidly aggregated, queried, and reviewed. TeleWatch also has two-way store-and-forward messaging capability. This allows health care providers to leave voice messages for specific patients or system-wide messages to be played each time a person from a particular cohort accesses the system. This feature facilitates education and information dissemination to both individuals and cohorts of patients. In addition, patients can leave voice messages or questions to which health care providers can respond.

Although commercial products exist that collect data from patients, TeleWatch is unique because of its portability, scalability, and two-way voice messaging capability. Furthermore, TeleWatch was designed with the capabilities required for use in an effective disease management program, not as a stand-alone system that is often poorly incorporated into health care delivery systems.

Design

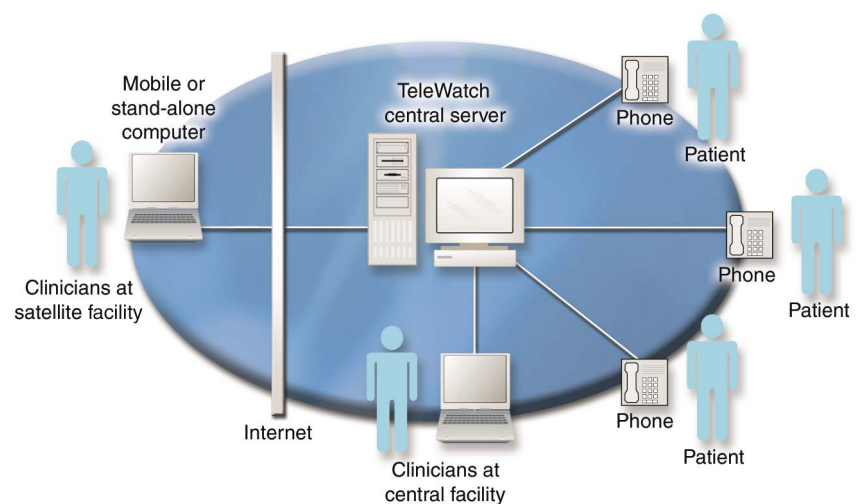The design of TeleWatch was driven by the following goals:

Figure 1. TeleWatch System deployment.

- Minimization of cost while maintaining the system's reliability
- Use of technology with which patients and health care providers would feel comfortable
- System capacity for several hundred patients/users, with the potential to accommodate thousands of patients in the future
- Maximization of patient data integrity and security, including full compliance with the Health Insurance Portability and Accountability Act (HIPAA)

Hardware

With these requirements, the TeleWatch System was designed as a client–server application, with the Tele-Watch server provided by one or more Windows servers that patients access through standard telephone lines. The interface between these phone lines and the Tele-Watch server is made via an Intel Dialogic Interactive Voice Response board installed in the server. In low-capacity environments, a D4PCI board is used for this telephone connection, which serves up to four analog lines. For higher-capacity loads, boards are available that support a T1 connection with 24 digital lines. Interactive Voice Response boards, which support voice recognition in lieu of key entry by the caller, are also available but have not yet been installed.

Client workstations access the server via a local area network or the Internet. Currently two unique configurations have been constructed and a third has been designed. The server configuration with the lowest capacity consists of a desktop PC with an MS Access database engine and a single four-line phone board that can support client PC connections via a local area network. This configuration can adequately serve 100 patients, each calling once per day. A higher-capacity configuration that uses separate database and phone servers has also been constructed; it allows Internet-based client access via a password-protected Citrix server and can support 500 daily users. In addition, a configuration with an even greater capacity of 5000 or more callers per day has been defined; it uses multiple Windows servers supporting multiple T1 phone connections providing 24 phone lines per T1 connection. A Microsoft SQL Server is used for the database in these higher-capacity configurations, with remote client access via the Internet.

Software

TeleWatch software includes the eight programs depicted in Fig. 2. These programs work in concert and obtain patient-specific data from the TeleWatch relational database, which includes 30 unique tables. All permanent data are stored in the database, and all data interfaces among TeleWatch programs occur via the database. Use of standard SQL code permits either MS Access or the MS SQL Server to serve as the database. All application code is written in Visual Basic (VB)
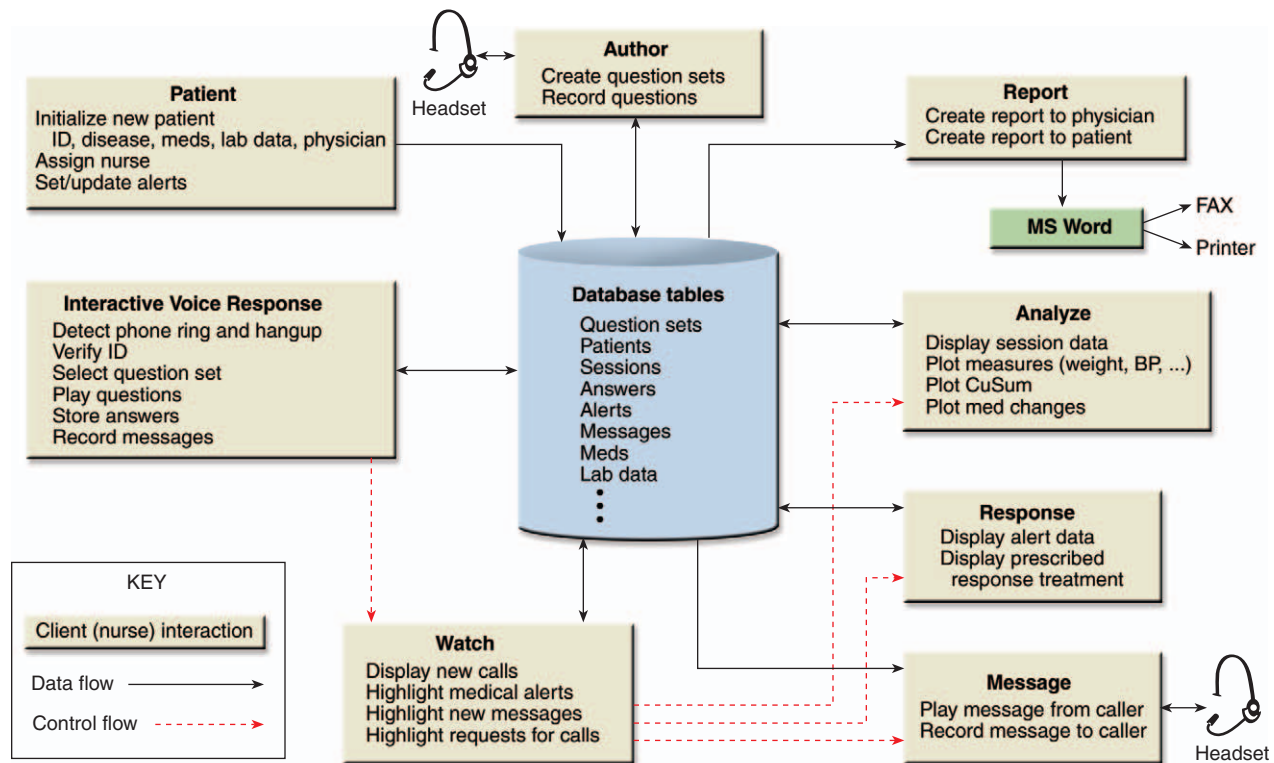

Figure 2. Software components of TeleWatch.

Version 6.0. In addition to features for building displays, the VB environment includes a comprehensive library of components to facilitate coding. Generation of reports and tables for printing or faxing is implemented by VB links to MS Word and Excel.

Disease-specific question sets are created in the Author program, and voice files are linked together to form question sets, also in the Author program. All questions within the TeleWatch System reside in a Master Questions table and may allow one of three types of responses: multiple-choice, numeric, or a prompt of the patient for a voice recording. For each question, a voice file is recorded by one of the health care providers using a headset connected to a PC. On-screen controls provide recording and playback links to an audio program that creates voice files with .wav format. Once the .wav file for each question has been recorded, a question set for each potential disease is assembled and ordered by dragging and dropping questions from the Master Questions list into the particular question set. This easy-to-use method of creating question sets facilitates the use of "local dialects" and familiar voices to query the patients, which increases patient acceptance of the system; it also allows rapid construction and modification of existing question sets.

Demographic and other relatively static data for each patient are entered via the Patient program. Each patient is assigned an identification code and an authentication code of at least four digits. In addition to demographic information, the patient's physician, recent laboratory data, and current medications may be entered into this program. For each question in the patient's assigned question set, alert conditions may be specified.

Caller interaction is provided via the local phone system by the Interactive Voice Response program. The Intel Dialogic products were selected for the capabilities they provide and for the ease of integration with the Windows environment. A software library of components provides the interface for reading key entries, playing recorded messages for and from health care providers, recording caller messages, and detecting hangups. Upon authentication of a caller's ID, the Voice program retrieves a question set tailored to the patient's disease, sequentially plays each question (taking into account question branching and rotating question groups), records each answer, and tests answers for predefined alert conditions. If any

of the questions prompt the caller to leave a message, the recording is stored in a .wav file.

Recent calls that have not been reviewed previously by a health care provider are displayed by the Watch program (Fig. 3). For each call session, the person's name and an alert count are displayed along with an indication that a message was left or a request to call was made. Clicking on the person's name invokes the Analyze program (Fig. 4), which displays a grid of all answers to questions for the past month. From Analyze, a plot of any numeric data can be displayed with an overlay of medication changes during the same time period. Returning to the Watch display, clicking on the alert count invokes the Response program, which displays details of the alerts and prompts for entering a response to each alert. Clicking on the Message indicator in Watch invokes the Message program, which provides a means to play the message and to record responses that will be played when the patient next calls.

Health care providers may request that a report be sent to the patient's physician using the Report program. Answers are retrieved from recent sessions to plot the patient's vital signs. Recent laboratory data and medications are tabulated. A free-form block is provided for the nurse to add comments and suggestions. Text and graphics are formatted in MS Word, which facilitates editing by the nurse, printing, and storage for future reference.

Not shown in Fig. 2 is the Launcher program, which provides a login process local to the TeleWatch applications and a centralized screen to start any of those applications. The Launcher process is used in
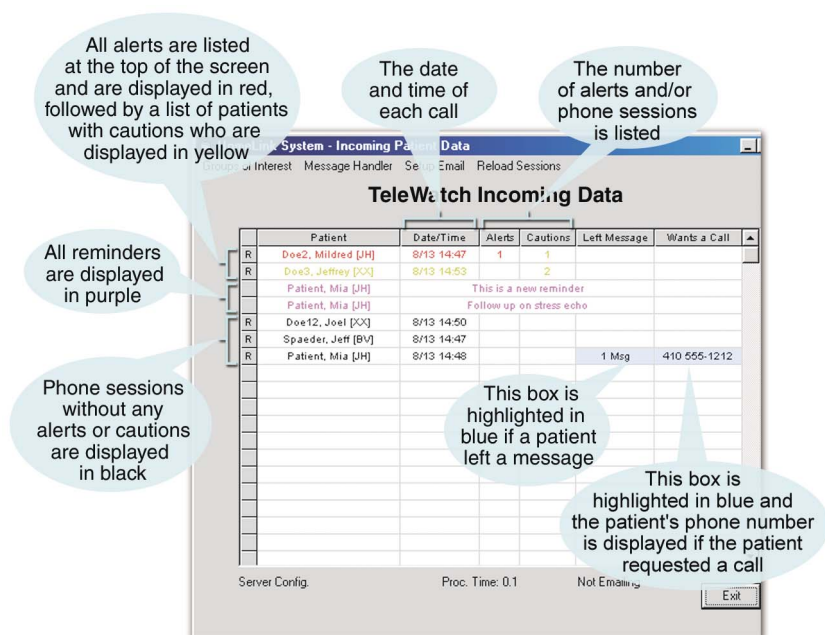

Figure 3. Example of the Watch screen.

Figure 4. Example of the Analyze screen.

conjunction with the Users program, which provides an administrator's screen for setting up password-protected login accounts and specifying the permitted patient access and program access permissions for each user. Access permissions provide a means to limit the data that each nurse or user may view or change. An Audit Log provides a detailed history of the data that were viewed or changed by each user. Access control and audits are the primary features required by HIPAA to ensure and manage patient privacy.

System data are also protected from inadvertent change or loss by a database backup process. Using the built-in features of the MS SQL Server, the entire database is backed up once per day and incrementally backed up every 3 h.

RESEARCH STUDIES

The TeleWatch System has been used to assess and adjust vasoactive medication and is currently being used in several ongoing studies involving disease management.

The Congestive heart-failure Carvedilol Up-Titration Study (C-CUTS) was an investigator-initiated trial designed and implemented by the applicant. The study was a randomized-control, physician-blinded study that enrolled adults with New York Heart Association Class II and III heart failure who were not taking a beta-blocker. C-CUTS was designed to assess whether the time required to achieve the maximally tolerated dose of the beta-blocker carvedilol was shorter in patients monitored with TeleWatch compared with aggressive clinic-based, outpatient monitoring (i.e., clinic visits every 2 weeks). Patients being monitored by TeleWatch were eligible for an increase in dose of carvedilol every week, whereas those in the control population were eligible for a dose increase during clinic visits. Titration decisions were made using a predefined algorithm. The data from this study have been analyzed, and an article is being readied for publication in peer-reviewed medical and health informatics journals.

One current study involves outpatients with congestive heart failure (CHF) enrolled in specialty CHF clinics at Johns Hopkins Outpatient Center and Johns

Hopkins Bayview Medical Center. TeleWatch is also an integral component of an ongoing research study at Johns Hopkins Health Care (JHHC) involving outpatients across the state of Maryland with cardiovascular disease. The statewide disease-management research program at JHHC used TeleWatch to monitor a larger patient population. In the winter of 2001, patients with CHF or diabetes with a cardiovascular co-morbidity who received health insurance through one of the JHHC insurance plans were approached to participate in the study in which disease management was coordinated by a nurse case manager. The health status of the patient was monitored with TeleWatch. The maximum number of patients enrolled in this initiative was 202; an additional 150 patients have been enrolled at other times since initiation of the program. Patients called the TeleWatch server located in Glen Burnie, Maryland, on a regular basis and reported self-measured blood pressure, weight, serum glucose levels (if appropriate), and symptoms. The patients and the TeleWatch System were monitored by one of five nurse case managers located in specific geographic regions. This research is ongoing. Patient participation rates have been very high. In the first quarter after enrollment, 68% of the patients actively contacted Tele-Watch three times a week and 78% contacted the system at least twice a week. Patients had a very favorable response to using the system.

In addition, TeleWatch has recently been successfully deployed in Australia in the Congestive Heart-failure Assistance by Telephone (CHAT) Study co-sponsored by Monash University and the Australian National Heart Foundation. In this study, 600 people who suffer from heart failure will be randomized to usual care or outpatient monitoring with TeleWatch. Patients will be recruited mainly from rural portions of the country (the "outback") and will call the TeleWatch server located in Sydney. Nurses will monitor the patients and access TeleWatch from Adelaide, with researchers monitoring the progress of the study in Melbourne (Fig. 5). Periodic system maintenance and updates will be performed from APL.

CONCLUSIONS

Patient acceptance of the TeleWatch Patient Monitoring System has been favorable. Patients with chronic illnesses find the system easy to use and like the fact that their health is closely monitored. Health care providers can intervene in the event of a clinical deterioration and provide focused feedback much more efficiently. This close monitoring should allow providers to make appropriate interventions more rapidly and lead to improved clinical and financial outcomes. In addition, since TeleWatch performs the basic medical monitoring and triaging of patients in parallel, a single
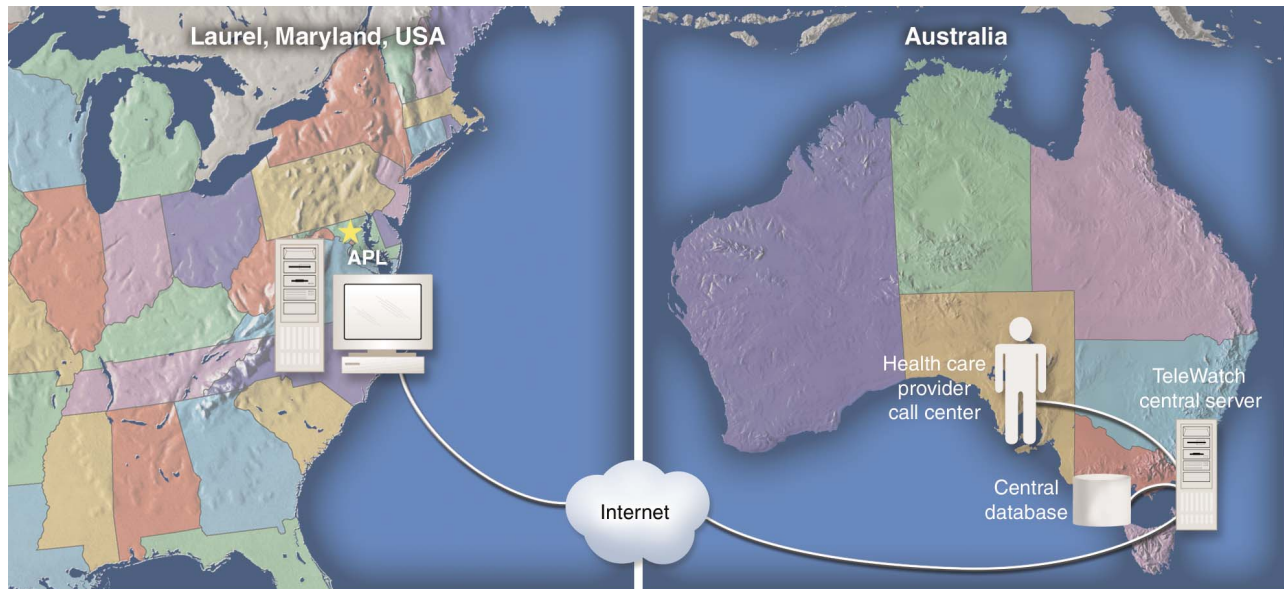
Figure 5. TeleWatch deployment in the CHAT Study.

provider can treat larger numbers of patients than is possible in a traditional office-based environment. These capabilities are essential, given the expected rapid increase in the numbers of Americans with chronic illnesses.

Future research and development of TeleWatch will include incorporation of additional noninvasive monitoring capabilities without sacrificing the system's simplicity and inexpensive design. The success in monitoring patients with cardiovascular illnesses suggests that other conditions (e.g., diabetes, hypertension, obstructive lung disease, infectious diseases, and cancer) and populations requiring frequent monitoring may also benefit from this method of outpatient management, and plans are under way to deploy TeleWatch in these other areas. Furthermore, as a larger number of Americans become computer and Internet savvy, Internet-based monitoring will be added. However, the telephone-based data entry pathway will likely remain well into the future because it is easy to use and widely available.

Despite the early success of the TeleWatch technology, the effectiveness of the system also depends on nontechnical issues such as proper selection of patients, integration into routine clinical care, and physician reimbursement for time spent monitoring patients. Without careful study of these issues, the TeleWatch System and other telemedicine systems will not be incorporated into routine clinical practice.

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